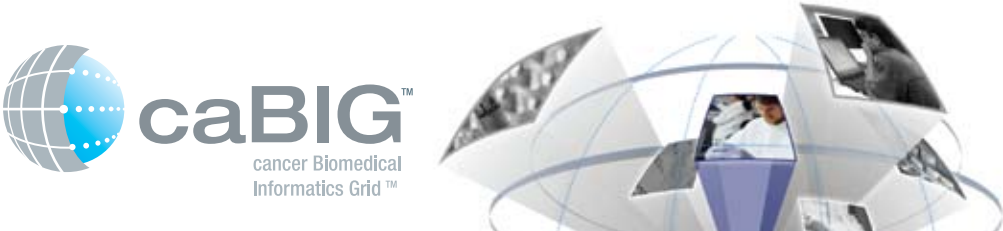


Getting Connected with caBIG®

DATA SHARING AND SECURITY FRAMEWORK



Component	Specific Objective	Description	Cancer Center Participation Role
caBIG® Analytical Tools and Policies <ul style="list-style-type: none">caBIG® Data Sharing and Security Framework (DSSF)<ul style="list-style-type: none">DSSF Decision Support ToolAdditional Decision Support Tools<ul style="list-style-type: none">Human Research ConsiderationsPrivacy ConsiderationsContractual ConsiderationsIntellectual Property ConsiderationscaBIG® security policies for authentication (identity management) and authorization	Facilitate the evaluation of the level of data sensitivity and the corresponding level of access controls the institution will require for each data set to be shared	The DSSF provides an organization with a conceptual framework and implementation tools that assist Centers in preparing to share data via the caBIG® infrastructure and that assist with overcoming barriers that may exist in data sharing. The DSSF implementing tools include decision support tools that provide guidance about the four separate analyses which are required to assess the sensitivity of any given dataset and to determine the desired data access controls. The current versions of the DSSF tools may be found on the Data Sharing and Intellectual Capital (DSIC) Knowledge Center website at https://cabig-kc.nci.nih.gov/DSIC/KC/index.php/Tool_Library . The caBIG® security policies and procedures set forth the requirements for providing the software and procedural infrastructure that provide the levels of access controls for each dataset as determined by the data-providing institution.	Centers are expected to participate in the testing and refinement of the DSSF by evaluating the available DSSF tools in a Center's workflow and providing feedback to the caBIG® program on the Center's experience with the tools. Centers will actively contribute to the testing of security controls by reviewing caBIG® policy statements and providing expert input on the various levels of data access protections from the institution's perspective.
Processes and Best Practices <ul style="list-style-type: none">Suggestions for conducting the informed consent process in a manner that permits data to be shared via the caBIG® infrastructure and utilizes model informed consent language as appropriate (see below)Expectations for sharing unpublished data (varies depending on data type)Recommendations regarding incentives for sharing unpublished dataSuggestions for developing contract clauses for sponsored research projects that permit broad data sharing, including the use, when appropriate, of model contract clauses (see below)Informational documents for IRB use in reviewing proposals for data sharing via the caBIG® infrastructure that utilizes, when appropriate, the caBIG® data sharing plan guidelines	Facilitate institutional approval of data sharing arrangements via the caBIG® infrastructure	Best practices, suggested conduct, and proposed recommendations that will inform the researcher and the institution of the advantages of sharing data and community-developed methods for encouraging and recognizing data sharing among researchers across departments within a single institution and located at different institutions.	The Center will be expected to participate in the evaluation and refinement of best practices and suggested guidance documents, to pilot their use for internal approval processes, and to provide recommendations for further refinement based on such experiences.
Model Documents <ul style="list-style-type: none">Standardized click-through agreements between data providers and users (e.g., data-related provisions in Data Use Agreements and Material Transfer Agreements)Security-related agreements (for both data providers and users)Model informed consent provisionsModel researcher questionnaires and data sharing checklistsModel contract clauses for sponsored research projects (including clinical trial agreements) to permit data sharing	Facilitate and expedite data sharing arrangements between institutions	Model agreements and other documents will expedite negotiations between institutions for sharing data by providing simple standard agreements for most low and medium sensitivity data sets.	Centers are expected to participate in the evaluation and refinement of model documents, to pilot their use for internal processes, and to provide recommendations for further refinement based on such experience.